

INSPECTION TECHNICAL PROCEDURE

I-104

DESIGN PROCESS ASSESSMENT

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INSPECTION TECHNICAL PROCEDURE I-104, REV. 2

DESIGN PROCESS ASSESSMENT

1.0 PURPOSE

This procedure assesses the adequacy of the Contractor's design process and the implementation of the design process procedures.

2.0 OBJECTIVES

This procedure assesses the adequacy of the design process program for implementing the Contractor's commitments in the authorization basis. Also, it assesses implementation of the Contractor's design process procedures in the design of structures, systems, and components (SSCs).

3.0 DEFINITIONS

The definitions included in the following references are incorporated by reference into this inspection procedure:

- DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the River Protection Project Waste Treatment Plant Contractor*, "Glossary."
- The RL/REG-97-05, *Office of Safety Regulation Management Directives*, "Glossary" (the glossary also includes a list of acronyms that are incorporated by reference into this inspection procedure).

4.0 BACKGROUND

The River Protection Project Waste Treatment Plant (RPP-WTP) Contract,¹ Section C, paragraph C.6, Standard 7: "Environment, Safety, Quality, and Health," commits the Contractor to implement the requirements of the authorization basis which include the requirements of an approved Quality Assurance Program and an approved Integrated Safety Management Plan (ISMP). The quality assurance requirements are described in the Contractor's Quality Assurance Manual (QAM).

¹ Contract DE-AC27-01RV14136 between DOE and BNI, dated December 11, 2000.

This inspection will assess the adequacy of the Contractor's design process and the implementation of the design procedures applied to all Quality Level items and activities as described in the QAM, Policy Q-02.1, Section 1-2, Quality Assurance Scope."

5.0 INSPECTION REQUIREMENTS

This inspection procedure will assess the adequacy of the Contractor's design process to meet the requirements in the authorization basis. The adequacy of the design process will be assessed by verifying that selected commitments included in the QAM and ISMP are included in engineering procedures and design documents used to control the design process. The inspectors will assess the level of implementation of these procedures by determining whether these procedures were used in the design of the selected SSCs and by observing activities currently in progress.

5.1 Design Procedures

The inspector should verify that the important-to-safety design process is controlled by and conducted in accordance with documented instructions, procedures, and drawings. (QAM, Policy Q-05.1, Section 3.1.1)

5.2 Design Input

- 5.2.1 The inspector should verify design inputs are identified and documented, and their selection reviewed and approved by the responsible engineering group. (QAM, Policy Q-03.1, Section 3.2.1; and NQA-1, Supplement 3S-1, paragraph 2)
- 5.2.2 The inspector should verify design inputs are specified and approved on a timely basis to permit the design activities to be carried out in a correct manner. (QAM, Policy Q-03.1, Section 3.2.2; and NQA-1, Supplement 3S-1, paragraph 2)
- 5.2.3 The inspector should verify the facility is being designed for a set of events that includes normal operations, anticipated operational occurrences, maintenance, and testing; external events; natural phenomena; and postulated accident conditions. With regard to accident conditions, the design will incorporate the expected environmental conditions into the specifications for the SSCs that must function to prevent hazardous situations or mitigate the consequences of accidents. (ISMP, Sections 1.3.3, 1.3.4, 1.3.5, 3.6.3 and 3.13; and SRD, SC 4.1-3 and 4.3-2)
- 5.2.4 The inspector should verify human factors specialists identify opportunities early in the design phase for design improvements and provide recommendations to address human factors principles and processes. (ISMP, Section 3.12)

5.3 Interface Control

- 5.3.1 The inspector should verify design effort is coordinated among participating organizations to ensure integration of design and other technical requirements into the design documents. (QAM, Policy Q-03.1, Section 3.3.1; and NQA-1, Supplement 3S-1, paragraph 6)
- 5.3.2 The inspector should verify design information transmitted across interfaces is identified and controlled. (QAM, Policy Q-03.1, Sections 3.3.2 and 3.3.4; NQA-1, Supplement 3S-1, paragraph 6; and SRD, Safety Criterion (SC) 4.1-2)

5.4 Design Process

- 5.4.1 The inspector should verify appropriate standards are identified and documented, and their selection reviewed and approved. (QAM, Policy Q03.1, Section 3.4; and NQA-1, Supplement 3S-1, Paragraph 3)
- 5.4.2 The inspector should verify the design methods, materials, parts, equipment, and processes, essential to the function of the items, are selected and reviewed for suitability of application. (QAM, Policy Q-03.1, 3.4.4; and NQA-1, Supplement 3S-1, paragraph 3)

5.5 Design Analysis

- 5.5.1 The inspector should verify calculations are controlled and are retrievable. (QAM, Policy Q-03.1, Section 3.5.4; and NQA-1, Supplement 3S-1, Paragraph 3.1)
- 5.5.2 The inspector should verify design analyses documentation includes the objective, inputs and their sources, background data, assumptions, computer calculations and identification of the originator, reviewer and approver. (QAM, Policy Q-03.1, Section 3.5.5; and NQA-1, Supplement 3S-1, Paragraph 3.1)
- 5.5.3 The inspector should verify computer program acceptability has been pre-verified or the results verified with the design analysis for each application. (QAM, Policy Q-03.1, Sections 3.5.6 and 3.5.7)

5.6 Design Verification

- 5.6.1 The inspector should verify design verification has been performed prior to releasing the design to another organization for other design activities. Any unverified portion of the design shall be clearly identified and controlled. (QAM, Policy Q-03.1, Section 3.6.3; NQA-1, Supplement 3S-1, paragraph 4)
- 5.6.2 The inspector should verify project engineering procedures provide for appropriate levels of design review and verification, evaluating correct design inputs, adequate

descriptions of reasonable assumptions, design method, correct incorporation of design inputs, reasonableness of design output when compared to design inputs, and the specification of necessary design input and verification requirements for interfacing organizations, as applicable. In addition, for specified aspects of the design, procedures include a requirement that engineering documents be checked by personnel with technical qualifications comparable to the originator and design verification be performed by any competent individual or group other than those who performed the original design. (QAM, Policy Q-03.1, Sections 3.6.1, 3.3.3, and 3.7.1; and NQA-1, Supplement 3S-1, paragraph 4)

5.7 Qualification Tests

The inspector should determine if any part of design adequacy is to be verified by qualification tests, and if so, verify the tests will be in accordance with Policy Q-11.1. (QAM, Policy Q-03.1, Section 3.9.1)

5.8 Design Change Control

- 5.8.1. The inspector should verify design criteria is established and all changes to the design is controlled to ensure changes to the design or design documents, created by design change notices, construction field changes (field change notices or field change requests), nonconforming items, or procurement originated changes, are controlled by measures commensurate with those applied to the original design. (QAM, Policy Q-03.1, Sections 3.14 and 3.10.1 A and NQA-1, Supplement 3S-1, paragraph 5)
- 5.8.2 The inspector should also verify procedures prescribe the process needed to identify, status, and communicate ongoing design changes to ensure consistent system integration and configuration control throughout the design organization. (QAM, Policy Q-03.1, Section 3.10.1 and NQA-1, Supplement 3S-1, paragraph 5)

5.9 Software Design Control

The inspector should verify any designed or developed software used in the design process is appropriately documented, approved, and controlled. (QAM, Policy Q-03.1, Section 3.11.1)

5.10 Audits

The inspector should verify audits are performed on selected design documents to ensure the effectiveness of the design program. (QAM, Policy Q-018.1, Section 3.1.1)

6.0 INSPECTION GUIDANCE

The inspector should be familiar with the design related requirements set forth in the QAM, NQA-1, and ISMP.

6.1 Design Procedures

The inspector should gain a broad understanding of the system used to control design. Policies, procedures, instructions, drawings and computer programs all must be integrated together to ensure control and consistent practices. In addition to the general understanding of the system, the review of procedures and other documentation for the inspection attributes listed below will all contribute to a view of the Contractor's program for controlling design. The word "procedures," as used in this inspection guidance should be read as procedures, codes of practice, and/or other appropriate design documents.

6.2 Design Inputs

- 6.2.1 The inspector should review the procedures used to control the identification, review, documentation, and approval of design inputs to ensure appropriate involvement by the engineering group responsible for the design. Also, the inspector should review three design packages to confirm the procedures were followed.
- 6.2.2 The inspector should review procedures that control configuration management from the onset of design. The timeliness of inputs and approvals should be addressed. The inspector should also review three design packages. Look at the timeliness of inputs and the documentation necessary for design decisions, design verification measures, and evaluating design changes.
- 6.2.3 The inspector should examine a design package which includes equipment which must function during accident conditions to determine if it addresses all of the attributes specified in Section 5.2.3.
- 6.2.4 The inspector should review procedures which address the manner in which human factor considerations are incorporated into the design process. Human factor specialists should be interviewed to determine the manner and timeliness of their input into the design process.

6.3. Interface Control

- 6.3.1 The inspector should review procedures that control design interfaces between organizations. The inspector should verify that the selected procedures address coordination of design inputs among participating organizations. Individuals in a least two different organizations should be interviewed to determine if their practices have followed the procedure.

- 6.3.2 The inspector should review procedures that control the flow of design requirements from other design functions (e.g., hazards analysis or accident analysis) to the design responsible engineer. The inspector should verify the procedures address identification, review, approval, release, distribution, revision, and control of design information passed between the participating design organizations. Transmittals must also identify the status of the design information and identify any incomplete items that require further evaluation, review or approval.

6.4 Design Process

- 6.4.1 The inspector should examine three design packages and verify appropriate important-to-safety (ITS) identification, review and approval of standards. Any changes to the selected standards should show the reasons for the change, and that it is properly controlled.
- 6.4.2 The inspector should review procedures that control the content and distribution of the listed materials, parts, equipment, and processes that are essential to the function of ITS items. The procedures should require that all ITS items and activities are identified in a list, and the list is used across the project for design, procurement, construction, and operation activities. Commercial grade items must be identified with the acceptance criteria defined for such items to be verified.

6.5 Design Analysis

- 6.5.1 The inspector should review design analysis procedures to ensure design analysis calculations are identified by subject, originator, reviewer, date or other designations. Any alternate calculations must meet the requirements of NQA-1, Policy Q-03.1, Section 3.8.
- 6.5.2 The inspector should examine three design packages to determine if they contain all the information specified in the requirement. The documentation should be sufficient that a technically qualified person could verify the results without recourse to the originator.
- 6.5.3 The inspector should review the Contractor's file for computer program verification to ensure that any programs used for analysis/calculations have been properly verified.

6.6 Design Verification

- 6.6.1 The inspector should determine if any completed design has been transferred or released to another organization for other design activities, and if so should confirm that the design had been properly verified.
- 6.6.2 The inspector should review the procedures for design verification, review and approval of work, and engineering calculation, preparation, checking and approval. The inspector

should verify that the selected procedures address the appropriate level of review of engineering documents and that engineering documents are checked by independent personnel with technical qualifications comparable to the originator.

6.7 Qualification Tests

The inspector should determine by discussion if any part of design adequacy is to be verified by qualification testing. If so, the inspector should review any procedures that are pertinent, and review at least one design package. Test requirements and acceptance criteria must be specified, and test results must be evaluated against the acceptance criteria.

6.8 Design Change Control

- 6.8.1 The inspector should review procedures for managing changes to control the Authorization Basis and the procedures referenced therein. The inspector should verify that the procedures selected control design criteria and design changes commensurate with the measures applied to the original design.
- 6.8.2 The inspector should select those procedures that identify, status, and communicate design changes, such as change control and drawing and document control. The inspector should verify that the selected procedures identify, status, and communicate design changes that ensure consistent system integration and configuration control throughout the design organization.

6.9 Software Design Control

The inspector should review the requirements of QAM, Policy Q-03.2, Software Quality, the Contractor's software QA plan, and any written policies. These should provide for control of any software which is developed by the Contractor or purchased. The Contractor also should provide direction on verification and validation of any software being used. The inspector should refer to the last Configuration Management Assessment conducted for previous reviews in this area.

6.10 Audits

The inspector should verify that the selected procedures require that QA reviews be performed on selected design documents. These documents normally address appropriate quality requirements, QC inspection requirements, and QA criteria. The inspector should review at least the last QA audit report of the design program and any other surveillances or audits which may have been conducted. The inspector should determine if there were any significant findings, and if so, the corrective actions which were taken.

7.0 REFERENCES

DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the River Protection Project Waste Treatment Plant Contractor*, Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

Integrated Safety Management Plan, BNFL-5193-ISP-01, Rev. 6, Bechtel National, Inc., Richland, Washington, 2001.

Quality Assurance Manual 24590-WTP-QAM-QA-01-001, Rev. A, Bechtel National, Inc., Richland, Washington, 2001.

ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*, 1989 Edition

RL/REG-97-05, *Office of Safety Regulation Management Directives*, "Glossary," Rev. 2, U.S. Department of Energy, Office of River Protection, 2001.

Safety Requirements Document, BNFL-5193-SRD-01-02, Bechtel National, Inc., Richland, Washington, 2001.

8.0 LIST OF TERMS

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| BNI | Bechtel National, Inc. |
| ISMP | Integrated Safety Management Plan |
| ITS | important-to-safety |
| QA | quality assurance |
| QAM | Quality Assurance Manual |
| QC | quality control |
| QL | Quality Level |
| RPP-WTP | River Protection Project Waste Treatment Plant |
| SC | Safety Criteria |
| SRD | Safety Requirements Document |
| SSC | structures, systems, and components |

Attachments: None